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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/580,077

04/23/2007

Diana Helen Pliura

RAM-PT015

8083

3624 7590 02/01/2010

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EXAMINER

HIRIYANNA, KELAGINAMANE T

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

02/01/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/580,077	Applicant(s) PLIURA ET AL.	
	Examiner KELAGINAMANE T. HIRIYANNA	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-132 is/are pending in the application.
- 4a) Of the above claim(s) 79-116 and 121-132 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-78 and 117-120 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/06; 09/06; 05/07; 12/08</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed on 10/28/2009 in response to office action mailed on 09/29/2009 has been acknowledged.

Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Restriction of invention

Applicant's election with traverse of restriction requirement in the reply filed on October 29, 2009 is acknowledged. Applicant elects with traverse the invention Group I (Claims 1-78 and 117-120) for further prosecution on merits. The Applicant traverses on the grounds that a search for all groups and species would not be burdensome. The applicants arguments are, found not persuasive because the applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicant's election of species restriction in the reply filed on October 29, 2009 is acknowledged.

Claims 1-78 and 117-120 are pending and presently under examination.

Claims 79-116 and 121-132 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected claims, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-78 and 117-120 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-78 and 117-120 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

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regards as the invention. The use of the terms “about”, “approximately” and “substantially” in the claims renders them vague and indefinite. Appropriate corrections are required.

claims 1 & 41 and their respective dependent claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The claim recitation “pH of the liposome composition” makes the claim vague and indefinite because the liposomes can have different pH for the aqueous solution encapsulated inside lipid layers than in the aqueous suspension medium for said liposome and one of skill in the art is unclear as to which of this aqueous portion of the liposome composition, the Applicant is referring to. Further clarification is required.

Claims 1-5, 41-45, and 127 contain the limitation “the amino group of lipophilic amine”. Such is unclear to one of skill in the art which amino group the applicant is referring to as many of the lipophilic amines contain more than one amino group. Hence, the claim is rejected for lack of clarity.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-78 and 117-120 are rejected under 102(b) as being anticipated by Camu et al., (Patent No. US 6,149,937).

The above claims are drawn to a stable liposome composition comprising a suitable aqueous medium and at least one pharmaceutical agent and drawn to said liposome that is sterile.

Camu discloses a stable liposome composition for delivering a pharmaceutical agent wherein in said liposome is stable and comprises aqueous medium (entire article; abstract). Camu further teaches that said pharmaceutical liposome compositions are prepared by hydrating a film comprising phospholipids including phosphatidyl-choline as well as cholesterol (entire

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article; abstract; col.3 lines 15-68 bridging col.4; col.7, lines 26-54) and further encapsulates said pharmaceutical compound in an aqueous medium at an acidic pH range from 4-6.5 etc., (col.7, lines 55-67 bridging col.8) and wherein said pharmaceutical compounds include various lipophilic amines that include anesthetics, morphine and opioids including fentanyl etc and with pK ranges between 3.5-10.5 (col.5, Table II; col.8, lines 22-30). Sterilizing liposome compositions for used as pharmaceuticals or therapeutic purposes inherent in the prior art. Thus the rejected claims are within the scope of the Camus's disclosure.

Claims 1-78 and 117-120 are rejected under 102(b) as being anticipated by Mezei et al., (Patent No. US 5,451,408/ US RE38,407E).

The above claims are drawn to a stable liposome composition comprising a suitable aqueous medium and at least one pharmaceutical agent and drawn to said liposome that is sterile.

Mezei discloses a stable liposome composition for delivering a pharmaceutical agent wherein in said liposome is stable sterile and comprises aqueous medium (entire article; abstract; col.4-10). Mezei further teaches that said pharmaceutical liposome compositions are prepared by hydrating a film comprising phospholipids including phosphatidyl-choline as well as contain sterols, ethanol, and appropriate salts in the encapsulated medium with pH of 7.4 (entire article; abstract; col.5 lines 3-22; col.6) and further encapsulates said pharmaceutical compound in an aqueous medium and suspended in sterile aqueous media (col.7, lines 55-67 bridging col.8) and wherein said pharmaceutical compounds include various lipophilic amines that include anesthetics, morphine and opioids including fentanyl etc (with pK ranges between 3.5-10.5) (col.5, lines 61-65 bridging col.6; col.10-12). Thus the rejected claims are within the scope of the Mezei's disclosure.

Conclusion:

No claim allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Kelaginamane Hiriyanna Ph.D.*, whose telephone number is **(571) 272-3307**. The examiner can normally be reached Monday through Thursday from 9 AM-7PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Joseph*

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Woitach Ph.D., may be reached at **(571) 272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

/Robert M Kelly/

Primary Examiner, Art Unit 1633